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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,804	06/20/2001	Lea Eisenbach	EISENBACH 3	6094

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/744,804	EISENBACH ET AL.	
	Examin r	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the c v r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2003 and 24 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,16,19-21,23,24,26-34,44,45 and 53-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,16,19-21,23,24,26-34,44,45 and 53-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/2003 has been entered.

Claims 1, and 16 are amended, and claim 58 is new. Claims 1, 16, 19-21, 23, 24, 26-34, 44, 45, and 53-58 are pending and examined on merits.

The ext of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejection.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of the claims 1, 19, 20, 21, 23, 24, 26-34, 44, 45, and 53-57 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

On reconsideration, the rejection of claims 26-29, and 32-34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement

is withdrawn because the issues raised for the claims reciting "pharmaceutical" or "vaccine" is enablement, not written description.

The rejection of claims under 35 U.S.C. 112, first paragraph, scope of enablement is withdrawn because applicant at page 12 of the amendment filed on 9/24/2003 argues that HLA peptide binding prediction using a computer software is possible and the Office could not meet the burden that the computer software predicted HLA peptide binding does not work.

The rejection of claims 1, 19-21, 23, and 44 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn because the instant claims are interpreted as drawn to MCH class 1 binding 9-10 peptides from an art-known sequences i.e., BA-46 and applicant argument that HLA peptide binding prediction is possible at the current state of art is persuasive.

Claim Rejections - 35 USC § 112, Maintained

Claims 24, 26-34, 45, and 54 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are interpreted as drawn to pharmaceutical or vaccine whose main ingredient is MCH class 1 binding 9-10-mer BA-46 peptides.

Applicant's argument traversing the written description rejection above been fully considered; applicant argues at page 7 of the amendment filed 9/24/2003 that the Office is not considering how CTLs are formed and does not understand the instantly claimed invention, and go on to explain how the claimed peptides treat cancer by generating cancer-devouring CTLs. Applicant also argues that the specification at Table 7 at pages 38-40 teaches seven human BA-46 predicted to bind with HLA-A2, binds to chimeric HhD well, BA-46 are immunogenic shown at Fig. 13-17. As stated previously, the specification does not disclose any in vivo data using the instantly claimed products. Carmon et al shows that BA-46 stimulated CTLs, not the instantly claimed prodcut reduce tumor growth. The specification does not disclose any in vivo data that instantly claimed peptide could reduce tumor growth and applicant does not argue with this statement. The therapy shown at Carmon et al is cell therapy and instantly claimed invention is drawn to peptide therapy. The rejection is maintained because the art teaches that pharmaceutical comprising peptide vaccine is still unpredictable at the current state of art and its effectiveness could not be extrapolated from in vitro data as shown in instant Figs. 13-17; a publication well after the effective filing date of the instant application, Belllone et al, (09/01/2000, J Immunol., vol. 165, page 2651-6) teach in Table 1 that only dendritic cells pulsed with Trp-2 181-188 immunodominant T cell epitope worked to protect the experimental mice against cancer. The last row of Table 1 in Bellone et al shows that administering the Trp-2 181-188 immunodominant T cell epitope directly to mice did not work, even though the identical peptide is used in both instances.

Considering the state of art, limited guidance and no working example of pharmaceutical and/or vaccine comprising instantly claimed peptides in the instant specification, one skilled in the art would have question about the efficacy of the claimed vaccine or pharmaceutical. It is concluded that undue experimentation involving clinical sample is required in order to practice instant invention.

In order to obviate this rejection, applicant is invited to present experimental data showing that administration of instant claimed peptides, not administration of cells stimulated with the instantly claimed peptides actually work in vivo to reduce tumor growth.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 16, 19-21, 23, 44, and 55-58 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 16, 19-21, 23, 44, 55-58 as written, do not sufficiently distinguish over peptides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "purified". See MPEP 2105.

Claim Rejections - 35 USC § 112

Claims 1, 19-21, 23, 24, 26-34, 44, 45, 53, 54, and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 19, 20, 21, 23, 26-34, 44, 45, 53, 54, and 58 are interpreted as drawn to MHC type 1 T cell epitope consisting of 9-10 contiguous amino acid residues from Lactaherin (BA-46). There is a lack of written description for Lactaherin (BA-46), a genus of polypeptides that are defined by a name, i.e. actaherin (BA-46).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity.

The specification at page 38, 3rd paragraph says that only human Lactaherin (BA-46) is known in the art. The specification does not teach the chemical structure(s) of any Lactaherin (BA-46) other than saying that a human Lactaherin (BA-46) sequence is known in the art. It appears that any other Lactaherin (BA-46) sequence had not been known in the art before the effective filing date of the instant application. Instant

claim 19 and 20 recite "a mammal" and "a rodent". What is Lactaherin (BA-46) of dog, a mammal? What is the Lactaherin (BA-46) of hamster, a rodent? There is not even identification of any particular portion of the Lactaherin (BA-46) structure that must be conserved in all of mammals. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus of Lactaherin (BA-46).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of Lactaherin (BA-46), given that the specification teaches that a human Lactaherin (BA-46) is known in the art. Therefore, only the art known Lactaherin (BA-46) described in at page 38, 3rd paragraph of the instant application, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is separable from its enablement provision (see page 1115). A definition by function alone "does not suffice, to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lily*, 119 F.3 at 1568, 43 USPQ2d at 1406.

Conclusion

Although a human and a mouse BA-46 sequences and its expression in breast cancer are well known in the art, for example US Pat. 5, 455,031, 103 obviousness rejection for instantly claimed 9-10 peptide from BA-46 is not made because the Office could not meet the burden why one would be motivated to find peptide promotes effective binding to MHC class 1 type.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne C Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Misook Yu

February 9, 2004

LARRY R. HELMS, PH.D
PRIMARY EXAMINER